

REMARKS

These remarks are in response to the Final Office Action dated May 2, 2007. Claims 1, 3, 9, 11-16 and 25-31 are pending. Claim 11 has been cancelled. Claim 1 has been amended to recite the subject matter of cancelled claim 11. The present Amendment places the application in condition for allowance for the reasons discussed herein; and does not raise any new issues requiring further search and/or consideration as the amendments amplify issues previously discussed throughout prosecution. Claims 1, 3, 9, 12-16 and 25-31 are pending and at issue. Entry of the Amendment is respectfully requested.

II. FORMAL MATTERS***Information Disclosure Statement***

An information disclosure statement under 37 CFR §1.97(e)(2) accompanies the present Reply. The statement is provided in fulfillment of Applicants duty of disclosure, candor and good faith under 37 CFR §1.56. However, the filing of this statement shall not be construed as an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR §1.56 (see 37 CFR §1.97(h)). Applicants request entry and consideration of the information disclosure statement.

1) References Cited in Accompanying IDS

Provided below is a brief description of the information contained in Japanese Laid-Open Patent No. S50-83323 and Japanese patent publication No. S52-35648. These references are also identified in the 1449 form which accompanies the present Reply.

Japanese Laid-Open Patent No. S50-83323 discloses that an acrylamide aqueous solution is likely to polymerize under low pH conditions. In addition, an acrylamide solution is quite reactive and liable to form impurities under high pH conditions. Accordingly, an acrylamide solution should be kept as neutral as possible during a purification process (see e.g., page 2, upper right column, line 5-8 of patent no. S50-83323). Japanese patent publication No. S52-35648 discloses that an acrylamide aqueous solution lacking a stabilizer is liable to polymerize. This

characteristic is particularly prevalent when the pH is low, for example, at 3.0 or less (see e.g., page 2, column 3, lines 6-11 of publication no. S52-35648).

The processes disclosed in the references discussed above are distinguishable from the processes claimed in the instant application. Based on the information provided in the references, the skilled person would not subject an amide compound-containing solution to acidic conditions to, for example, remove proteins from the amide compound-containing solution having unsaturated bonds.

Rejections Under 35 U.S.C. §112, first paragraph

Claims 1, 3, 9, 11-16 and 25-31 stand rejected under 35 U.S.C. §112, first paragraph, as purportedly failing to comply with the written description requirement. This rejection is moot with regard to cancelled claim 11. Applicants traverse this rejection as it may apply to the amended claims.

At page 2, part 3, paragraph 3, of the Office Action, the Examiner asserts that "recitation of the name 'nitrile hydratase' and its source as a microorganism fungus body do not define any structural features and amino acid sequences commonly possessed by the genus." The Examiner further asserts that the "specification does not describe and define any structural features and amino acid sequences commonly possessed by the genus."

The Examiner appears to take the position that, in order to satisfy the written description requirement of section 112, the specification is required to recite the amino acid sequence of every nitrile hydratase useful in the present method. In the absence of such extensive information, the Examiner suggests limiting the claimed method to a specific bacterial nitrile hydratase encoded by a specific polynucleotide sequence (see page 3, lines 8-11 of the pending office action).

Applicants submit that the combination of the instant disclosure coupled with the knowledge of the skilled artisan sufficient describes a genus of nitrile hydratases that may be used in the claimed method. Those of ordinary skill in the art were aware that nitrile hydratases are hydrolytic enzymes responsible for the sequential metabolism of nitriles in some bacteria and fungi and were capable of utilizing aliphatic nitriles as the sole source of nitrogen and carbon. Thus, those of ordinary skill in the art would have recognized from reading the disclosure that the inventors

had invented a method that accommodates the use of various nitrile hydratases, not just the exemplary enzymes set forth in the specification. Neither the claims, nor the specification need be more specific with regard to, for example, the structure of a nitrile hydratases useful in the present methods because the skilled artisan already has such information in his/her possession.

As noted previously, the novelty of the present method lies not in the particular nitrile hydratase used in the method, but instead lies in the combination of conditions identified by the Applicants as suitable for purifying an amide compound. The forced recitation of a specific hydratase in the claims is an unnecessary limitation on the claimed method. Further, the forced recitation of known sequences in the instant disclosure would only add unnecessary bulk to the specification. Accordingly, accessible literature sources clearly provided, as of the relevant date, information about nitrile hydratase from various sources including those deposited in accessible repositories.

In light of the above, Applicants submit the claims are supported by the specification such that the skilled artisan would understand the inventors had possession of the invention at the time of filing. Applicants request that this rejection be withdrawn.

Rejections Under 35 U.S.C. §103

Claims 1, 3, 9, 11-16 and 25-31 stand rejected under 35 U.S.C. §103(a) as purportedly unpatentable over Oriel et al. (WO 99/55719) ("Oriel") in view of Chen. (*J Biol Chem.* 1967 Jan 25;242(2):173-81) ("Chen"). Applicants traverse this rejection.

The Examiner alleges that the process taught by Oriel, as modified by Chen, inherently removes impurities including, but not limited to, proteins. The Examiner further alleges that the modified process involves not only contacting the solution with activated carbon, but also includes steps for concentrating or precipitating by distillation or evaporation the amide solution, thereby removing contaminating proteins.

The present claims are drawn to a method of purifying an amide compound by contacting a solution containing such a compound with activated carbon under acidic conditions (i.e., pH 3.5 - 6.5). Such conditions are conducive to removing protein

contaminants. The amide compound includes an unsaturated bond and is produced by contacting a nitrile compound with a nitrile hydratase, a microorganism fungus body containing nitrile hydratase or a processed product of the microorganism fungus body. Applicants were the first to discover that these conditions provide a purified compound with a high degree of reproducibility.

In contrast to the present claims, the methods disclosed by Oriel are not conducive to removing contaminating proteins present in an amide solution by concentrating the amide solution through distillation or evaporation. This is because the contaminating proteins have a higher boiling point than that of the amide compound set forth in the claimed method. Accordingly, the contaminating proteins can not be distilled and evaporated at the lower temperature than the boiling point of the amide compound and the process of Oriel et al. can not inherently remove impurities including proteins. Further, Oriel et al. fails to teach or suggest that the proteins are included in the amide solution produced by contacting a nitrile compound with a nitrile hydratase, a microorganism fungus body containing nitrile hydratase or a processed product of the microorganism fungus body.

It is clear from the specification of Oriel that the cited reference fails to appreciate the significance of contacting the reaction solution with activated charcoal under acidic conditions in order to facilitate the purification of the amide compound as set forth in the pending claims. As noted in the present specification, utilizing charcoal treatment under the acidic conditions present in the amide solution provides an efficient and reproducible mechanism for removal of proteins. This treatment is preferable to the charcoal treatment under "neutral conditions" taught in Oriel. Thus, while the cited reference recites a purification mechanism, Oriel clearly fails to disclose any method that utilizes acidic conditions of the reaction solution to facilitate the controlled purification of an amide compound. Accordingly, this reference supplies neither the motivation to use activated charcoal in conjunction with an acidic environment to arrive at a method as set forth in the pending claims, nor any expectation of success if one were to attempt it.

The secondary reference fails to remedy the deficiencies of Oriel because Chen fails to suggest an acid charcoal treatment to remove proteins from a solution containing amide compounds. There is simply no motivation in either Oriel or Chen

to use acidic pH conditions, particularly pH 3.5 to 6.5, in order to generate a method suitable for purifying an amide compound under the acidic conditions set forth in the pending claims, and certainly no teaching that such experiments would have any likelihood of success.

As a result, the skilled person would be not motivated to modify Oriol to remove proteins from amide-containing reaction solution, based on the disclosure of removing lipid impurities from proteins by Chen. In light of the above discussion, Applicants request that the rejections under 35 U.S.C. § 103 be withdrawn.

CONCLUSION

It is respectfully submitted that all rejections have been overcome by the above amendments. Thus, Notice of Allowance is respectfully requested.

In the event that there are any questions relating to this Amendment or the application in general, it would be appreciated if the Examiner would contact the undersigned attorney by telephone at (858) 509-7318 so that prosecution of the application may be expedited.

Respectfully submitted,

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